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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/406,832	09/28/1999	KEIKO YUGAWA	43888-067	1982

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EXAMINER
NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
1743	21

DATE MAILED: 12/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/406,832	Applicant(s) YUGAWA ET AL.	
	Examiner ALEX NOGUEROLA	Art Unit 1743	

-- Th MAILING DATE of this communication app ars on th cov r sheet with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5-19,22-36 and 39-53* is/are allowed.

6)☒ Claim(s) *20, 21, 37-38, 54-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 September 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *19* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claim Objections

1. Claim 38 objected to because of the following informalities: in line 4 the comma between "maleic" and "acid' should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 20, 21, 37, 38, 54, and 55-81 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended Claims 20, 21, 37, 38, 54, 55, 64, and 73 by substituting "collidine" for "colicin". Applicant alleges that "colicin" in the original claims was a typographical error. While not doubting Applicant's sincerity, "collidine" appears to be new matter because (a) the spelling of the two words are similar, but not very similar, (b) no occurrence of "collidine" has been found or cited in the original disclosure, and (c) collidine is significantly different from colicin in structure, properties, and function. Collidine is 2,4,6-trimethylpyridine (*Wiley Encyclopedia of Reagents*

for Organic Synthesis) while a colicin is a bacteriocin, which is most likely a peptide antibiotic (*Wiley Encyclopedia of Molecular Biology*). Thus, "collidine" appears to be new matter.

4. Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over English language translation of Heisei 10-227755 in view of the newly cited CAPLUS abstract of Maslinska-Solich (Chemia Stosowana (1990), 34(1-2), 11-22).

Addressing Claim 21, Heisei 10-227755 discloses a method for stabilizing glucose dehydrogenase for use in glucose sensors ([Means of solution] and second sentence in paragraph [0007]), wherein at least one additive is added to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline quinone ([Means of solution] and paragraph [0007]). Heisei 10-227755 also discloses a list of additives (paragraph [0007]) that includes maleic acid, which is in the Markush group of additives in Applicant's claim. It would have been obvious to one with ordinary skill in the art at the time the invention was made to choose maleic acid or a maleate from among the list of additives disclosed by Heisei 10-227755 in order to optimize the glucose sensor. Although, carboxymethyl cellulose showed the best performance (paragraph [0007]), this was for limited tests, such as an aqueous glucose solution ([Embodiment Example 1]). Heisei 10-227755 contemplates a variety of samples, such as blood, urine, or food products (paragraph [0013]). As shown by the abstract for the review article by Maslinsk-Solich it was known at the time of the invention that maleic anhydride is useful in isolating physiological active substances in clinical analysis of blood or urine.

Addressing Claim 38, Heisei 10-227755 discloses a glucose dehydrogenase composition for use in glucose sensors ([Means of solution] and second sentence in paragraph [0007]), the composition containing glucose dehydrogenase whose coenzyme is pyrrolo-quinoline quinone, and at least one additive ([Means of solution] and paragraph [0007]). Heisei 10-227755 also discloses a list of additives (paragraph [0007]) that includes anhydrous maleic acid, which is in the Markush group of additives in Applicant's claim. It would have been obvious to one with ordinary skill in the art at the time the invention was made to choose maleic acid or a maleate from among the list of additives disclosed by Heisei 10-227755 in order to optimize the glucose sensor. Although, carboxymethyl cellulose showed the best performance (paragraph [0007]), this was for limited tests, such as an aqueous glucose solution ([Embodiment Example 1]). Heisei 10-227755 contemplates a variety of samples, such as blood, urine, or food products (paragraph [0013]). As shown by the abstract for the review article by Maslinska-Solich it was known at the time of the invention that maleic anhydride is useful in isolating physiological active substances in clinical analysis of blood or urine.

9. Claims 55 and 59-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crismore et al. (US 5,997,817) in view of Vetter et al. (US 6,025,203) and Gotoh et al. (US 6,071,391).

Addressing Claims 55 and 59-63; Crismore et al. teach a glucose sensor comprising an electrically insulating base plate, an electrode system including at least a working electrode and a counter electrode formed on the base plate, and a reaction layer which is formed in contact with or in the vicinity of the electrode system wherein the reaction layer contains a sugar (trehalose); a

glucose dehydrogenase whose coenzyme is pyrrolo-quinoline; and a buffer (sodium succinate is implied to be a buffer in col. 6, ll. 41-46). See col. 5, ll. 60-67; col. 6, ll. 41-46; and col. 7, ll. 45-59. Sodium succinate is not in applicant's list of buffers in Claim 55. Vetter et al. teach a reagent layer comprising a glucose dehydrogenase whose coenzyme is pyrrolo-quinoline and citric acid, which applicant claims as a buffer. Citric acid buffers at pH 5.0 (Gotoh et al. col. 8, ll. 46-50) and sodium succinate buffers at pH "approximately 6.76 plus or minus 0.05" (Crismore et al. col. 6, ll. 41-46). So, barring evidence to the contrary, such as unexpected results, the choice of buffer is just a matter of the optimizing the pH for the sample. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use citric acid as taught by Gotoh et al. in the invention of Crismore et al. because this will buffer the pH at 5.0, which will be optimal for some samples.

For Claim 60, note that as shown by the CAPLUS abstract of Takahasi et al. ("Effect of a trehalose inhibitor, validoxylamine A, on three species of flies", Appl. Entomol. Zool. (1995), 30(1), 231-9), trehalose can be derivatized from glucose.

For Claims 62 and 63, note that as implied by the CAPLUS abstract of Cucinotta et al. (Three-dimensional cyclodextrin: a new class of hosts by trehalose capping of B-cyclodextrin", J. Inclusion Phenom. Mol. Recognit. Chem. (1996), 25(1-3), 39-42) trehalose can be synthesized from a dextrin derivative.

Allowable Subject Matter

10. Claims 5-19, 22-36, 39-53 are allowed.

11. The following is a statement of reasons for the indication of allowable subject matter:

a) Claims 5, 22, and 39: the prior art of record does not teach phthalic acid or phthalate in a reaction layer with glucose dehydrogenase whose coenzyme is pyrrolo-quinoline;

b) Claims 6-19 depend directly or indirectly from allowable Claim 5;

c) Claims 23-36 depend directly or indirectly from allowable Claim 22; and

d) Claims 40-53 depend directly or indirectly from allowable Claim 39.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JILL WARDEN can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola
December 15, 2002